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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/601,574

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John J. O'Mahony

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23117 7590 11/17/2008
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/601,574	Applicant(s) O'MAHONY ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 82-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,690,831 to Kenley et al.

In the specification and figures, Kenley discloses the apparatus as claimed by applicant. With regard to claims 82 and 84, Kenley discloses an extracorporeal circuit or sterile contiguous fluid line for infusing a patient 28 comprising a draw line portion 432 and return line portion 470 (see FIG 13). Return line 470 is directly fluidly connected to a patient access line portion 492 via pressure monitoring chamber 472. The circuit comprises a portion of the fluid line at 462 that is adapted to be interoperable with a pump actuator 458 (see FIG 13). The circuit further comprises filter 404 connected to the draw and return lines and blood sensor 486 (that acts as a blood leak detector) coupled to the fluid line at portion 492 (see FIG 13, column 33, lines 39-50). The pump disclosed by Kenley is operable in a forward direction (or first configuration) in which positive pressure is generated within the return line portion 470 and patient access portion 492 in order to return blood to a patient. The pump is further disclosed as being operable in a reverse mode (or second configuration), in which clamp 490 in patient access portion 492 is closed, the pump 458 is operated in reverse, drawing blood from

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line 492 back into line 470 until air is detected by air sensor 476 (see column 26, lines 58-64). Accordingly, reversing of the pump as disclosed by Kenley creates a negative pressure in the return line portion 470 and may reverse flow in patient access portion 492 to move fluid from line portion 492 upstream of clamp 490 upstream of chamber 472.

With regard to Applicant's limitation that the return line comprises a fluid passage substantially free of gases, Kenley discloses such an arrangement. In particular, when the fluid level in drip chamber 472 is above the tip of inlet tube 472 (see FIG 13), the return line is a continuous fluid passage substantially free of gases. Accordingly, Kenley suggests a continuous fluid line with no gases in an embodiment of the disclosed extracorporeal fluid loop.

With regard to claims 83 and 85, when pump 458 reverses direction in the claimed second configuration, it necessarily reverses direction of flow in each of the return line portion 470 and the draw line portion 432. Since the pump operates to move fluid through a circuit, each line comprises fluid that moves through the lines during operation of the pump in a particular direction. Since the pump is not operating in a vacuum, reversal of the pump direction necessarily causes reversal of flow on either side of the pump, meeting the limitations of the claims.

Response to Arguments

2. Applicant's amendments and arguments filed 4 August 2008 have been entered and fully considered, but are not persuasive.

3. Applicant argues that patient return line portion 470 is not connected to patient access portion 492 in the Kenley reference as set forth in the claims. The Examiner respectfully disagrees. The lines are directly fluidly connected to one another, as demonstrated by the fact that fluid flows from line 470 through chamber 472, through line 492, and back to the patient. Accordingly, it is the position of the Examiner that the lines are, in fact, in fluid connection via inlet tube 471 and chamber 472.

4. Applicant further argues that when the Kenley pump is reversed, patient access line portion 492 is clamped shut, such that no blood is drawn out of line 492, thus preventing the Kenley device from reversing flow in the patient access line as set forth in the amended claims. The Examiner respectfully disagrees. While Kenley discloses that clamp 490 is closed during pump reversal, the portion of line 492 that is above, or upstream of the clamp in the pump's forward operation, is still in fluid communication with the pump 458 when the pump reverses direction. Fluid moves from that upstream portion of line 492 through chamber 472 until it is in the area of line 470 defined as upstream of chamber 472 when the pump operates in a forward direction. As such, flow through at least a part of patient access line portion 492 is reversed in the Kenley apparatus.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
13 November 2008